K072276

MAY 16 2008

Section II 510(k) Summary of Safety and Effectiveness

1.	**510(k) owner:**	Xian Friendship Electronics Co., Ltd.
	Company address :	No.9 Gao Xin 1st Road, High-Tech Develop Zone, Xi'an, Shaanxi Province, 710075 P. R. China
	Phone number :	(86) 29 88225200
	Fax number :	(86) 29 88236285
	contact person:	Zhai Ying Chuan ,General Manager
	E-mail:	georgezhai2616@163.com
2	**Preparation date of the 510(k) summary:**	**11 May 2008**
3	**Device Name:**	Subdermal Needle Electrodes
	Common Name:	Subdermal Needle Electrodes
	Device Trade name:	(1) Subdermal Needle Electrodes (a)Subdermal Needle Electrodes-Single (b)Twisted Pair Needle Electrodes (c)Parallel Pair Subdermal Needle Electrodes (d)Dual Needle Electrodes (2)Disposable Concentric Needle Electrodes (3)Disposable Monopalar Needle Electrodes (4)Corkscrew (spiral) Needle Electrode Other clients private labeling
	Classification Name:	Needle Electrode
	Product Code:	GXZ

4. Identifies the legally marketed device to which equivalence is claimed

Predicate Devices	Manufacturer: Axon Systems, Inc. Trade Name: Subdermal Needle Electrodes FDA number: K050194 Manufacturer: Rhythmlink International, LLC Trade Name: Rhythmlink International Subdermal Needle Electrodes FDA number: K022914

Manufacturer: Medtronic Functional
Trade Name: Diagnostics A/S Disposable
Monopolar Needle Electrodes
FDA number: **K990375**

5. Description of device

Xian Friendship Electronics Co., Ltd.s' Subdermal Needle Electrodes are disposable (for "Single Use Only"),sterile devices used to detect electro-physiological signals or provide electrical stimulation subcutaneously.
The electrodes are the interface medium between the diagnostic or monitoring equipment and the patient. The subdermal needle electrode is comprised of a small gauge stainless steel needle on one end electrically connected to lead wire and a "touch-proof' safety connector on the other end. The needle is inserted subdermally by a licensed physician or technologist under the supervision of a physician. The safety connector is connected to recording or monitoring equipment.
The safety connector is an industry standard DIN 42802 protected, "touch proof' connector and cannot be connected to an AC outlet.
Electrodes are used in clinical electro-diagnostic studies or intraoperative monitoring which may include electroencephalography (EEG), electromyography (EMG) or evoked potentials recording and electrical stimulation.
Subdermal Needle Electrodes are invasive since they are positioned subcutaneously and are used under the supervision of a licensed physician.

6. The intended use

Xian Friendship Electronics Co., Ltd.' Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation/recording equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals and for stimulation during the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction.

7. Indications for Use

Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation/recording equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals and for stimulation during the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction. The electrodes are sterile and for single patient use only.

8. Summary of the technological Characteristics

Xian Friendship Electronics Co., Ltd.' s Subdermal Needle Electrode consists of an insulated wire, of various lengths, electrically connected to a small gauge, stainless steel needle on one end, and a DIN 42802 "touch-proof' safety connector on the other end. The connector is specifically designed so that it cannot be plugged into AC power outlet. The electrode is supplied in a sterile pouch. Materials used are the same as in the predicate devices.

9. Brief discussion of the nonclinical tests submitted

The materials of construction of the Subdermal Needle Electrodes are identical to those for the Axon Systems, Inc.'s Subdermal Needle Electrodes and Rhythmlink International Subdermal Needle Electrodes.
The safety feature and other functional and performance characteristics of the Subdermal Needle Electrodes are identical to those "Predicate Devices". Those features and characteristics were already verified and validated.

10.Brief discussion of the clinical tests submitted

Clinical studies were not deemed necessary regarding the Subdermal Needle Electrodes due to their similarity in materials, design and function to those "Predicate Devices". The device was evaluated by health care professionals during a simulated use test and was found to be acceptable for its intended use.

11. Biocompatibility testing

The contact material of the tip is a medical grade 304/316 series Stainless Steel. This material is of known biocompatibility.
And those materials were already tested for material safety and biocompatibility as indicated in previous 510(K) submissions, K050194 and K022914. Therefore, no new biocompatibility tests are necessary.

12. Conclusions drawn from the non clinical, clinical and biocompatibility tests

Xian Friendship Electronics Co., Ltd. s' Subdermal Needle Electrodes are substantially equivalent to the predicate devices. No new questions of safety or effectiveness are raised or evident.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Xian Friendship Electronics Co., Ltd.
% Beijing Easy-Link Company
Mr. Chu Xiaoan
Room 1606, Building 1. Jianxiang Yuan
No. 209 Bei Si Huan Zhong Road, Haidian District
Beijing, 100083, People's Republic of China

MAY 16 2008

Re: K072276
Trade/Device Name: Subdermal Needle Electrodes
Regulation Number: 21 CFR 882.1350
Regulation Name: Needle Electrode
Regulatory Class: Class II
Product Code: GXZ
Dated: May 11, 2008
Received: May 14, 2008

Dear Mr. Xiaoan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

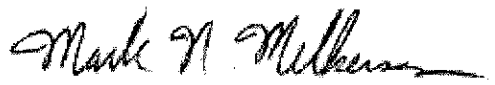
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section I INDICATIONS FOR USE

Applicant: Xian Friendship Electronics Co., Ltd

510(k) Number (if known): *

Device Name: Subdermal Needle Electrodes

Indications For Use:

Subdermal Needle Electrodes are intended for use with recording, monitoring and stimulation/recording equipment for the recording of biopotential signals including electroencephalograph (EEG), electromyograph (EMG) and nerve potential signals and for stimulation during the intraoperative diagnosis of acute dysfunction in corticospinal axonal conduction. The electrodes are sterile and for single patient use only.

Prescription Use ___ X ___ AND/OR Over-The-Counter Use ___
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Division Sign-Off)
FOR MARK MELKERSON
Division of General, Restorative, and Neurological Devices

510(k) Number K072276

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)